



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: August 19, 2020

SUBJECT: Efficacy Review for White,
EPA Reg. No. 777-128
DP Barcode: 458943
E-submission No. 53155

FROM: Kristen Willis, Chief *Kristen Willis*
Product Science Branch
Antimicrobials Division (7510P)

TO: Eric Miederhoff, PM31
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Antimicrobials Division (7510P)

APPLICANT: Reckitt Benckiser, LLC
One Phillips Parkway
Montvale, NJ 07645

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl (40% C ₁₂ , 50% C ₁₄ , 10% C ₁₆) dimethyl benzyl ammonium chloride	0.960%
Octyl decyl dimethyl ammonium chloride.....	0.720%
Dioctyl dimethyl ammonium chloride	0.288%
Didecyl dimethyl ammonium chloride	0.432%
<u>Other Ingredients</u>	97.600%
Total.....	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Concentrated Liquid (Dilutable)

Submission type: Label Amendment

Currently registered efficacy claim(s): Concentrated liquid laundry pre-soak disinfectant treatment (bactericidal and virucidal) and non-food contact laundry sanitizer.

Requested action(s): Submission of confirmatory efficacy data to support a formulation change

Documents considered in this review:

- Cover letter from applicant to EPA dated 7/29/2020
- Two efficacy studies
 - MRID 51239501 dated 7/14/2020
 - Study dated 6/8/2020 (no MRID)
- Confidential Statement of Formula (EPA Form 8670-4)
 - Summary of CSFs, basic through alt #24
 - A justification dated 8/19/20 was provided upon request for testing of Formula e0220-083A to support the substantially similar formulation Alt. #14*
 - Basic formulations #1-#6 dated 6/22/2020
 - Alternate Formulations #7-#24 dated 7/29/2020
 - Efficacy testing was conducted on e0220-083A which is substantially similar to e0081-444A CSF Alternate #14 (Energy/Crisp Linen)
- EPA-approved label dated 08/07/2020

*Upon review of the justification, it is acceptable for testing conducted with e0220-083A to support Alternate CSF #14 and the remaining alternate CSFs (#7-#14).

II PROPOSED DIRECTIONS FOR USE

“DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

(Read the entire label before using the product.)

(For Laundry Sanitizer) (For Laundry Sanitization) (Directions)

(For) Single Dose (use) (for) (all washing machine (types)(styles)):

Add (full) contents of (pack)(package)(sachet) to your fabric softener (drawer)(compartment) or directly to the rinse cycle.

For (Standard)(Top Load) (Non-HE) (Non High Efficiency) Machine(s):

Add (150 mL) ((X) (cap(s)) (capful(s))) (each) filled to (level)(line) (X) of the dosing (cup)(cap)) to the fabric softener (compartment)(drawer) (of the washing machine) or directly to your rinse cycle wash.

[Place Holder for Dosing Cap Graphics]

For (High Efficiency)(HE)(Front Load) Machine(s):

Add (100 mL) ((X) (cap(s)) (capful(s))) (each) filled to (level)(line)(X) of the dosing (cup)(cap)) to the fabric softener (compartment)(drawer) (of the washing machine) or directly to your rinse cycle wash. (If total amount does not fit, add the remaining amount into the (compartment)(drawer) when rinse cycle wash begins.)

[Place Holder for Dosing Cap Graphics]

To Sanitize: add to rinse cycle and leave product in (contact)(rinse cycle) for 16 minutes.”

III STUDY SUMMARIES

1.	MRID	51239501	Study Completion Date:		07/20/20	
Study Objective		Laundry Sanitizer				
Testing Lab; Lab Study ID		Reckitt Benckiser LLC; M1781-003-v1.0				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Staphylococcus aureus</i> ATCC 6538				
Test Method		ASTM E 2274-16 Standard Test Method for Evaluation Of Laundry Sanitizers				
Application Method		Liquid concentrate				
Test Substance Preparation	Name/ID	Lysol Laundry Sanitizer e0220-083A				
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	e0081-455A				
	Preparation	Tested concentration: nominal Dilution: 1:173 (1 part test substance + 172 parts diluent) (v/v)- 2.89 mL of product into 500ml of water 1:10 fabric to test substance (weight/weight) Diluent: 400 ppm AOAC synthetic hard water				
Soil load		N/A				
Carrier type, # per lot		100% cotton, plain weave 1" x 1.5"				
Test conditions		Contact time	15 minutes 30 seconds	Temp	20°C	RH -
Neutralizer for Carriers		D/E Neutralizing broth				
Neutralizer for Wash Water		D/E Neutralizing broth				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		This study was not conducted under GLP. COAs were provided on request (Letter dated 8/18/20) Quat concentration: 2.28% Upon request, RB confirmed that D/E Neutralizing broth was used as the neutralizer as the report was unclear. RB also confirmed that 1:10 fabric to test substance ratio (weight/weight) was used.				

2.	MRID	N/A	Study Completion Date:		06/08/20	
Study Objective		Laundry Sanitizer				
Testing Lab; Lab Study ID		Reckitt Benckiser LLC; M1781-002-v1.0				
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Staphylococcus aureus</i> ATCC 6538 <i>Klebsiella pneumoniae</i> , ATCC 4352				
Test Method		ASTM E 2274-16 Standard Test Method for Evaluation Of Laundry Sanitizers				
Application Method		Liquid concentrate				
Test Substance Preparation	Name/ID	Lysol Laundry Sanitizer e0220-083A and e0081-439				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	e0220-083A (e0220-083A, e0220-087A) and e0081-439 (e0081-439, e0081-441)				

		NOTE: The testing for e0081-439 is not being evaluated since it is unclear which CSF this would support.					
	Preparation	<p>Tested concentration: Nominal 1:173 (1 part test substance + 172 parts diluent) (v/v)- 2.89 mL of product into 500ml of water Dilution: 1:173 (1 part test substance + 172 parts diluent) (v/v)- 2.89 mL of product into 500ml of water 1:10 fabric to test substance (weight/weight) Diluent: 400 ppm AOAC synthetic hard water</p>					
Soil load		N/A					
Carrier type, # per lot		100% cotton, plain weave 1" x 1.5"					
Test conditions		Contact time	16 minutes	Temp	20°C	RH	-
Neutralizer for Carriers		D/E Neutralizing broth					
Neutralizer for Wash Water		D/E Neutralizing broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		<p>This study was not conducted under GLP. COAs were provided on request (Letter dated 8/18/20) Quat concentration: 2.26% Upon request, RB confirmed that D/E Neutralizing broth was used as the neutralizer as the report was unclear. RB also confirmed that 1:10 fabric to test substance ratio (weight/weight) was used. "On both test dates, May 13th and 21st of 2020, the Wash Water Numbers Control (NC) recovery for <i>S. aureus</i> was slightly below the required minimum of 1.0×10^4 CFU (4 log₁₀). On May 13th the Wash Water NC recovery of <i>S. aureus</i> was 4.95×10^3 (3.69 log₁₀) and on May 21st the Wash Water NC recovery of <i>S. aureus</i> was 8.47×10^3 (3.93 log₁₀). Since the Wash Water NC recovery was below the valid minimum, the formulations were not able to meet the minimum reduction of 99.9% (3 Log₁₀) for the wash water. Due to both batches of both formulations having no recovery on any of the test swatches (<10 colony forming units recovered for all), it was concluded that both formulations would likely have no <i>S. aureus</i> recovery in the wash water due to there being a higher level of difficulty for organism reduction on the swatches compared to the wash water. There is also passing data for two batches of each formulation."</p>					

IV STUDY RESULTS

Laundry Sanitization

MRID	51239501
15 minutes 30 seconds contact time, 1:10 fabric to product ratio, dilution in 400 ppm hard water	
Batch	e0220-083A
Test Date	7/14/20
CFU/mL of inoculum	3.95 x 10 ⁸
Control Average Log ₁₀ CFU/carrier	3.98 x 10 ⁶
Test Average Log ₁₀ CFU/carrier	1.0
Log reduction for Test Carriers	5.6
Control Log ₁₀ CFU for Wash Water Control	4.56
Test Log ₁₀ CFU of Wash Water	1.0
Log reduction for Wash Water	3.56

MRID	N/A			
16 minutes 30 seconds contact time, 1:10 fabric to product ratio, dilution in 400 ppm hard water				
Formula	Staphylococcus aureus			
Organism	Staphylococcus aureus		Klebsiella pneumoniae	
Batch	e0220-083A	e0220-087A	e0220-083A	e0220-087A
Test Date	5/13/20	05/20/20	5/13/20	05/20/20
CFU/mL of inoculum	4.5 x 10 ⁸	4.5 x 10 ⁸		
Control Average Log ₁₀ CFU/carrier	6.42	6.63	5.22	5.51
Test Average Log ₁₀ CFU/carrier	1	1	1	1
Log reduction for Test Carriers	5.42	5.63	4.22	4.51,1
Control Log ₁₀ CFU for Wash Water Control	3.69	3.93	5.07	4.95
Test Log ₁₀ CFU of Wash Water	1.0	1.0	1.0	1.0
Log reduction for Wash Water	2.69*	2.93*	4.07	3.95

*The minimum log reduction (3-log) was not met for the wash water controls for *Staphylococcus aureus* as the control counts were too low to measure a 3-log reduction. The study for MRID 51239501 was conducted in order to repeat the *Staphylococcus aureus* tests.

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support alternate CSFs #7-24?
51239501	Laundry sanitizer	Fabric	1:173 (1 part test substance + 172 parts diluent) (v/v)	15 minutes 30 seconds	N/A	400 ppm AOAC Hard Water	• <i>Staphylococcus aureus</i> ATCC 6538	Yes
N/A				16 minutes			• <i>Staphylococcus aureus</i> ATCC 6538	No
							• <i>Klebsiella pneumoniae</i> , ATCC 4352	Yes

VI LABEL COMMENTS

Label Date/Identification Number: August 07, 2020

1. The approved label claims that the product, White, EPA Reg. No. 777-128, is a laundry sanitizer against the following bacteria for 16-minute contact time.
 - Staphylococcus aureus ATCC 6538
 - Klebsiella pneumoniae, ATCC 4352

The confirmatory data support alternate CSF's #7-24 and the claims are **acceptable** as they are supported by the submitted data.

2. No changes to the label are needed.